Remarks

I. Status of the Application and Claims

As originally filed, the present application had a total of 18 claims. Claims 2-4, 8, 9 and 14-18 were cancelled in a previous response to an Office Action. Claims 6, 7 and 10-12 have been withdrawn as the result of a restriction requirement but are subject to possible rejoinder at allowance. Thus, the claims now pending are 1, 5 and 13.

II. The Amendments

Claim 1 was amended in paragraph d) to eliminate the words "has or is likely to develop" and to introduce the phrase "is at increased risk of having ovarian cancer relative to the general population." The latter matches the language used in the preamble of the claim and serves to eliminate the use of the claimed method solely for predictive purposes.

The Rejections

On pages 2-8 of the Office Action, claims 1, 5 and 13 are rejected based upon the enablement requirement of 35 U.S.C. § 112, first paragraph. The Examiner argues that the specification only demonstrates that EDN levels in *urine* samples are indicative of the presence of ovarian cancer. The Examiner also argues that the claimed method is only fully enabled with respect to the diagnosis of ovarian cancer and not to determining whether a woman is at increased risk of developing this disease at some future time.

In response, Applicants are somewhat confused by arguments suggesting that the claimed method should be limited to the use of urine samples, since it should be clear that the claims are already limited in this way. Paragraph a) of claim 1 refers to a "test biological sample of urine" and paragraph d) to "control biological samples of urine." Since the remaining claims are dependent upon claim 1, this requirement extends to them as well. Thus, all claims expressly require that urine samples be used. If the Examiner would like to suggest some other language to make this more clear, Applicants will be happy to give this consideration. However, it is respectfully submitted that there should not be a need for this as the claims already comply with the Examiner's requirements.

Applicants also believe that, as amended in paragraph d), claim 1 (and by extension all the other claims as well) comply with the Examiner's suggestion that claims be limited to a determination of whether a woman has ovarian cancer and not whether she may develop it at a later time. The preamble of claim 1 and paragraph d) now refer to "increased risk of *having* ovarian cancer relative to the general population." Applicants used this language rather than simply referring to a determination whether a woman has ovarian cancer because it more accurately reflects the way in which tests of this type are used, *i.e.*, as part of an overall clinical evaluation to determine whether a woman has ovarian cancer. The actual diagnostic process would probably start with a physician taking a medical history of a subject, progress to a variety of tests (including the EDN test described herein) and might ultimately conclude with a biopsy. The claimed method may be considered analogous to the PSA test used in diagnosing prostate cancer which may provide an indication that a man is at increased risk of having prostate cancer but is not by itself dispositive because there are other factors besides the presence of disease that may sometimes cause an elevation. This certainly does not mean that the test is not useful or that it is not patentable.

It is worth noting that the claims do *not* refer to determining whether a woman is at "increased risk of *developing* ovarian cancer relative to the general population." The Examiner seems to read the phrase in this way on page 6 of the Office Action but there is a clear distinction. To say that a method can be used to determine if a woman is at "increased risk of *developing* ovarian cancer" suggests that a woman being examined may not have disease at all at the time the method is carried out but that an elevated level of EDN correlates with the later occurrence of the disease. In contrast, saying that a method can be used to determine is at "increased risk of *having* ovarian cancer," merely recognizes that there may be other causes of an elevated EDN reading besides ovarian cancer or that an error may have been made during the test that resulted in a false positive. In other words, it recognizes the method as one tool in a diagnostic procedure. It does not suggest that EDN levels are elevated in women who will later develop ovarian cancer.

In light of the amendments made herein, Applicants believe that the present claims comply with all of the Examiner's arguments concerning enablement and should be allowable.

Conclusion

In light of the amendments and discussion above, Applicants believe that all of the Examiner's rejections have been overcome. It is therefore respectfully requested that these rejections be withdrawn and that the claims presently pending in the application be allowed. Early notice to this effect is earnestly solicited.

If, in the opinion of the Examiner, a phone call may help to expedite the prosecution of this application, the Examiner is invited to call Applicants' undersigned attorney at (240)683-6165.

Respectfully submitted,

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